



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,473	07/27/2006	David Harold Drewry	PR60714USW	1716
23347	7590	02/18/2010	EXAMINER	
GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B482 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			RAO, DEEPAK R	
			ART UNIT	PAPER NUMBER
			1624	
			NOTIFICATION DATE	DELIVERY MODE
			02/18/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM
LAURA.M.MCCULLEN@GSK.COM
JULIE.D.MCFALLS@GSK.COM

Office Action Summary	Application No.	Applicant(s)	
	10/597,473	DREWRY ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8,9 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9 is/are allowed.
- 6) ☒ Claim(s) 1-5,8 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20091015</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the amendment filed on October 15, 2009.

Claims 1-5, 8-9 and 14 are pending in this application.

Withdrawn Rejections/Objections:

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

The following rejections are maintained:

Claims 1, 5 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al., WO 2004/089286 (International filing date: April 2, 2004 and effective filing date: April 4, 2003). The reasons provided in the previous office action are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'Ding et al. reference does not disclose any compound wherein the substituent corresponding to R2 of the instant claims is aryl optionally substituted with the substituents listed in the claim'. First, the definition provided for R2 was not very clear as it contained multiple "and" terms following the recitation of "group consisting of", separating the various substituent groups, thus it could not be accurately determined whether the terms following each of the "and" were part of the substituent list or part of R2 definition. As applicant submits on record that R2 is defined to represent aryl, optionally substituted with the

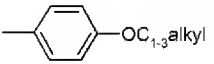
Art Unit: 1624

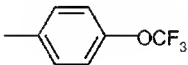
groups recited in that indent, it is understood that R2 does not represent any group other than an optionally substituted aryl, wherein the substituents are as provided in the claim.

Note: The definition of R2 will be in clear form if it is amended as:

-- R2 is aryl, optionally substituted by one or two groups selected from the group consisting of halogen, hydroxy, cyano, C₁₋₄alkyl, C₁₋₄alkoxy, C₁₋₄alkanoyl, haloC₁₋₄alkyl, haloC₁₋₄alkoxy, aryl, aryloxy, C₁₋₄alkoxycarbonyl, C₁₋₄alkylsulfonyl, **and** a group R₃R₄NSO₂ (wherein R₃ and R₄ are independently hydrogen or C₁₋₄alkyl), (CH₂)₀₋₃NHCOOC₁₋₄alkyl, and a 5- or 6-membered heteroaryl group; --

Next, applicant argues that 'Ding et al. does not teach or suggest a class of compounds having the particular combination of substituents recited in claim 1 and particularly, the

substituents corresponding to Y₁ or Y₂ which are defined to represent , and the

reference exemplified compound contains  at the equivalent position'. As

previously indicated, the reference teaches a generic group of pyrimidine compounds and further discloses several compounds within that genus, see for example, the species of compound 73 (depicted at page 5 of the previous office action). As submitted by applicant, the instantly claimed compounds differ by having a trifluoromethoxy group as the *para*-substituent on the phenyl ring as compared to an alkoxy (or more specifically a methoxy) according to the instant claims. The reference, however, teaches the equivalency of alkoxy and halo-substituted alkoxy groups as these are disclosed to be alternative substituents on the phenyl ring. Therefore, the reference clearly suggests to one of ordinary skill in the art the compounds of the instant claims. One of ordinary skill in the art in possession of the reference disclosed compound with the

Art Unit: 1624

disclosed activity would have immediately recognized that a single change in substitution such as changing the chloro substituent and replacing with another substituent which is taught to be equivalent, can be done without the loss of the pharmacological activity taught for the compounds. A single change in substitution of the reference disclosed compound would have resulted in a compound falling within the claimed genus.

Further, applicant argues that ‘the reference compounds are useful as inhibitors PDGF-R, c-Kit, and Bcr-abl as compared to the instantly claimed compounds which concern inhibition of ROCK activity’. This is not found to be persuasive because one of ordinary skill in the art based on the reference teachings would have been motivated to prepare the structurally analogous compounds (e.g., by having an alkoxy instead of the haloalkoxy substituent taught for the reference disclosed compound) with the reasonable expectation of obtaining compounds having properties consistent with the properties of the reference compounds. There is nothing on the record to show that the reference compounds do not possess the activity of the instant compounds. Applicants must prove that the claimed compounds possess a property that the prior art compounds do not possess. If the prior art compound does in fact possess a particular activity or benefit, even though the activity or benefit is not recognized in the prior art, applicant's recognition of the activity or benefit is not in itself sufficient to distinguish the claimed compounds from the prior art. The discovery of additional use not disclosed in the reference does not make otherwise obvious compounds unobvious. See *In re Best*, 195 USPQ 430 (CCPA 1977). As indicated above, one of ordinary skill in the art would have been motivated to prepare compounds that are structurally analogous to the reference compounds, i.e., by substituting one substituent with another equivalent substituent, with the reasonable expectation of obtaining

Art Unit: 1624

compounds having properties consistent with the properties of the reference compounds.

Applicant's arguments citing *KSR International Co. v. Teleflex Inc.* are fully considered but they were not deemed to be persuasive. The prior art is not limited just to the reference being applied, but includes the understanding of one of ordinary skill in the art. "*KSR* forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness" *Ex parte Smith*, USPQ 2d (BPAI June 25, 2007).

The following rejections are necessitated by the amendment:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 8 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The structural formula (I) of claim 1 is confusing because it appears to indicate that there is an attachment between R1 and the phenyl ring due to the presence of the dotted line (-----). Since the claim has been amended to remove the definition of the 'dotted line', it is suggested the formula be replaced with a structural formula that does not contain a dotted line. The specification at page 9 discloses such structural formula (see line 6), which would more accurately represent the genus of the instant claims.

Allowable Subject Matter

Claim 9 is allowed. Claims 2-4 and 8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Receipt is acknowledged of the Information Disclosure Statement filed on October 15, 2009 and a copy is enclosed herewith.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1624

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**/Deepak Rao/
Primary Examiner
Art Unit 1624**

February 16, 2010